

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KOLOSSOV *et al.*

Appl. No.: 10/561,780

§ 371 Date: July 2, 2007

For: **Tissue Modeling In Embryonic  
Stem (ES) Cell System**

Confirmation No.: 5875

Art Unit: 1632

Examiner: NOBLE, Marcia Stephens

Atty. Docket: 2590.0030002/EJH/SAC

**Reply to Restriction Requirement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Madam Commissioner:

In reply to the Office Action dated June 5, 2009, Applicants hereby provisionally elect to prosecute the claims of Group II, represented by claims 1-16, 40-42, 45, 49, 63 70-75, and 80. Applicants note that the subject matter of amended claims 1, 4, 7, 9, 10, 11, 12, 13, 15, 16, 40, 45, 49, 70-75 and 80 presented in the accompanying preliminary amendment is believed to pertain to Group II. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with traverse**.

Applicants respectfully assert that this Restriction Requirement based on lack of unity of invention is unfounded. According to 37 C.F.R. § 1.475(a), "a national stage application shall relate to one invention only *or to a group of inventions so linked as to form a single general inventive concept*." *Id.* (emphasis added). The Manual of Patent Examining Procedure (M.P.E.P.) provides the following guidance regarding "a single general inventive concept:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as

meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

M.P.E.P. § 1893.03(d) (Rev.6, Sept. 2007) at 1800-208; see also, 37 C.F.R. § 1.475(a).

The Examiner asserts that the claims of groups I-XXV allegedly do not share a corresponding special technical feature, as the technical feature in claim 1 is not special in view of Rambhatla et al. (U.S. Patent No. 6,458,589; hereinafter "Rambhatla."). *See* the Office Action at pages 4-5. Applicants respectfully disagree.

In the present case, the corresponding special technical feature that is common to groups I-XXV is the co-culture of at least two ES-derived cell types that are allowed to *integrate and align into tissue or tissue-like structures*. This feature is present in all of the pending claims, and therefore links the claims as a single general inventive concept under PCT Rule 13.1. As such, the claims in groups I-XXV should be grouped and examined together.

Contrary to the Examiner's assertion, Rambhatla does not disclose this corresponding special technical feature. The Examiner states that Rambhatla teaches the limitation "of allowing the cells to integrate and align into a tissue like structure" because Rambhatla teaches the formation of embryoid bodies from a mixed cell population. *See* Office Action at page 5. However, embryoid bodies are not the same thing as a tissue or tissue-like structure. For example, Figures 2B and 3C of the present application show that embryoid body formation is an early step in the method which ultimately results in the integration and align of at least two cell types into tissue or tissue-like structures. *See* Figures 2B and 3C. Thus, Applicants respectfully submit that Rambhatla does not disclose the corresponding special technical feature common to Groups I-XXV of the

instant application. Accordingly, the claims of Groups I-XXV should be grouped and examined together.

Moreover, Applicants note that the application was considered to have unity of invention during the international phase. Since a search and examination has already been carried out during the international phase, it would place absolutely no burden on the Examiner to examine all of the present claims.

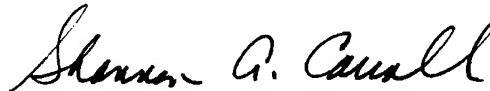
In addition, at a minimum and as the Examiner has indicated on page 4, Groups I and II should be rejoined as these claims are all drawn to a method of obtaining tissue or tissue-like structures by culturing an embryonic stem (ES) cell-derived first cell type in the presence of at least one embryonic second cell type; and allowing integration and alignment of said at least two cell types into tissue or tissue-like structures. The type of cell that is cultured is the only difference between these groups. As such, Applicants assert that searching and examining these groups together would not be a serious burden on the Examiner as references relevant for each would be found in the same search.

Thus, as indicated above, Rambhatla does not disclose the corresponding special technical feature of Groups I-XXV. Therefore, Applicants believe that the claims in Groups I-XXV should be grouped and examined together. In addition, Applicants note that the application was considered to have unity of invention during the international phase. Therefore, it would place absolutely no burden on the Examiner to examine all of the present claims. Furthermore, at a minimum Groups I and II should be grouped and examined together as searching and examining these groups together would not be a serious burden on the Examiner. Accordingly, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Shannon A. Carroll".

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